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EXAMINER

SAQIB, C

ART UNIT

1646

PAPER NUMBER

DATE MAILED 10/16/98

Below is a communication from the EXAMINER in charge of this application

COMMISSIONER OF PATENTS AND TRADEMARKS

ADVISORY ACTION

THE PERIOD FOR RESPONSE:

- a) is extended to run _____ or continues to run _____ from the date of the final rejection
b) expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

Appellant's Brief is due in accordance with 37 CFR 1.192(a).

Applicant's response to the final rejection, filed 9/28/98 has been considered with the following effect, but it is not deemed to place the application in condition for allowance:

1. The proposed amendments to the claim and/or specification will not be entered and the final rejection stands because:

- a. There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.
- b. They raise new issues that would require further consideration and/or search. (See Note).
- c. They raise the issue of new matter. (See Note).
- d. They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
- e. They present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: _____

2. Newly proposed or amended claims _____ would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.

3. Upon the filing an appeal, the proposed amendment will be entered will not be entered and the status of the claims will be as follows:

Claims allowed: _____

Claims objected to: _____

Claims rejected: _____

However:

Applicant's response has overcome the following rejection(s): _____

4. The affidavit, exhibit or request for reconsideration has been considered but does not overcome the rejection because _____
see attachment

5. The affidavit or exhibit will not be considered because applicant has not shown good and sufficient reasons why it was not earlier presented.

The proposed drawing correction has has not been approved by the examiner.

Other

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Attachment to Advisory Action

Applicant's request for reconsideration filed 28 September 1998 has been received and considered. However, the arguments presented are not found persuasive for reasons that follow.

Applicant argues that the instant claims are directed to VEGF antagonists wherein one or more cysteines are mutated which inhibit the molecules from properly dimerizing. Applicant further argues that these molecules retain the ability to bind to the VEGF receptor and because the prior art does not demonstrate the receptor binding, then the claims cannot be anticipated.

Applicant then cites several pieces of case law regarding inherency, including Ex parte Skinner, *In re Oelrich*, *In re Marshall*. Applicant's arguments are noted, but do not appear to be on point with the instant fact situation and rejection. The instant claims are directed to a compound (a VEGF variant) which has a particular structure (an amino acid modification of at least one cysteine, wherein the amino acid modification inhibits the ability of the variant to properly dimerize) and has the ability to bind to VEGF receptors without activating the receptors. Therefore, the claims recite a structure (an amino acid modification) which results in a desired function. The rejection of the claims as anticipated by the prior art relies on the fact that the prior art compounds have the recited structural modification of the claims (see paper #2, page 7-8). The prior art does not disclose whether the compounds have the ability to bind to the VEGF receptor, but one would reasonably conclude that this would be inherent to the compounds of the prior art. One would make this conclusion because Applicant states that this is the result of such a modification (see claim 1). The case law which is most on point with the current situation is *In*

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re Swinehart and Sfiligoj (169 USPQ 226) which discusses functional language and inherency in that the “mere recitation of a newly discovered function or property, inherently possessed by things in the prior art, does not cause a claim drawn to those things to distinguish over prior art; additionally,” where Patent Office has reason to believe that functional limitation may be inherent, may require applicant to prove otherwise. Therefore, although the art is silent to whether the VEGF variants of the prior art which meet the structural limitations of the claims also possess the functional limitations of the claims, it is up to Applicant to show that the compounds of the prior art do not possess those limitations. Applicant states that inherency must be certain (see argument at page 3). However, this is not a correct assessment of Skinner. At 1789, Skinner states “before an applicant can be put to this burdensome task, the examiner must provide some evidence or scientific reasoning to establish the reasonableness of the examiner’s belief that the functional limitation is an inherent characteristic of the prior art.” The evidence that the functional limitation of the ability of the compounds to bind to the VEGF receptors is that the compounds have the same structure as that recited in the claims, therefore, the functional characteristics of those compounds should be the same, and therefore, the property of binding to the receptor without activation would be inherent, absent evidence to the contrary. Applicant’s reliance on *In re Marshall* is misplaced because the fact situation in *Marshall* was one of a method whereas the instant claims are directed to a compound. The Examiner would agree that claims to a method of using a compound for a particular method in which the compound was not known to have that particular activity would be novel because one cannot use it for a method if it

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is not known to have that property. However, the instant claims are directed to a compound in which the prior art meets all of the structural (i.e. physical) limitations and therefore, would be expected to also possess the recited functional limitations, and therefore, these functional limitations would be inherent to the compound of the prior art.

Applicant's arguments regarding the 103 rejections of the claims are not persuasive for the reasons provided above. The courts have determined the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best* , 195 USPQ 430, 433 (CCPA 1977).

Information Disclosure Statement

The information disclosure statement filed 26 July 1998 (paper #8) fails to comply with 37 CFR 1.97(d) because (1) it lacks a statement as specified in 37 CFR 1.97(e), (2) it lacks a petition requesting consideration of the information disclosure statement, and (3) it lacks the petition fee set forth in 37 CFR 1.17(i). It has been placed in the application file, but the information referred to therein has not been considered.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Saoud, Ph.D., whose telephone number is (703) 305-7519. The examiner can normally be reached on Monday to Friday from 8AM to 3PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached on (703) 308-2731. The fax phone number for this Group is (703) 308-0294.

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Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Christine Saoud, Ph.D.

October 13, 1998

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JOHN ULM
PRIMARY EXAMINER
GROUP 1800